

STATEMENT OF WORK

1. The Contractor shall support the research effort of the HIV and AIDS Malignancy Branch (HAMB), other branches in the Center for Cancer Research (CCR), National Cancer Institute (NCI), and to a limited extent intramural programs within other institutes by documenting, through longitudinal studies using comprehensive, state of the art psychometric testing and neuropsychological evaluation, the status of psychological abnormalities and developmental progress in behavior, cognition, and motor abilities of adults and children with chronic medical illness, such as HIV disease and cancer, enrolled on protocols in the NIH as well as appropriate control populations. In doing so, the Contractor will be directed by the Project Officer (PO), who will in turn be guided in part by the Chief of HAMB. The PO, in consultation with the Chief of HAMB, will determine which of the patients and disease groups, including appropriate control populations, will be tested. Subjects, including control populations will be recruited by HAMB (or other NCI) researchers. Not all NCI or NIH patients that fall in disease groups described herein will be tested.
2. The Contractor shall investigate the effect of antiretroviral therapy on these psychological functions as determined by the medical staff and when directed by the PO. Special attention shall be paid to the effect of highly active antiretroviral therapy on the natural history and response to therapy of patients with the three categories of HIV-related CNS effects (encephalopathy, CNS compromise, CNS apparently not affected). This shall be accomplished through serial assessment and possible comparisons of patients with normal control groups, historical control groups, and, if time permits, with appropriate medical control groups who are also seen and treated at the NCI or the NIH. The PO may identify additional groups.
3. The sample that shall be assessed is anticipated to be approximately 15 to 20 new pediatric and 5 to 10 new adult patients each year. In addition, the study population will involve approximately 80 pediatric HIV-infected patients that are currently enrolled in ongoing clinical trials. The contractor shall perform a comprehensive evaluation of each patient at baseline, at least annually during treatment, and/or at the end of the treatment period. In addition, partial, monitoring assessments shall be administered at interim periods (quarterly or semi-annually) dependent on the patient's age and the expected degree of interval change associated with the disease and/or treatment, but not less than 3 months from a comprehensive evaluation. The comprehensive evaluations shall generally include at least assessment of the following domains of function: General Intelligence, language, visual spatial, perceptual, and constructive abilities, attention and concentration, concept formation and judgment, fine motor coordination, executive function, adaptive behavior, learning and memory. Specific tests for both the comprehensive and the monitoring evaluations will be decided upon in discussion between PO and offeror. The ultimate responsibility will rest with the PO after discussion with the Branch Chief of HAMB. He or she will also receive input from the contractees, and other appropriate input as necessary. The tests may include but are not limited to the following: The Wechsler Intelligence Scales for Children-III, the Wechsler Adult Intelligence Scales-3, Clinical Evaluation of Language Fundamentals 3, Verbal Fluency, Ravens Progressive Matrices, Ravens Coloured Progressive Matrices, Beery Developmental Test of Visual Motor Integration, Grooved Pegboard, The Trail Making Tests, Wisconsin Card Sorting Test, BRIEF (behavioral report of individual executive functioning), Vineland Scales of Adaptive Behavior, the Connors Behavioral Rating Scale, BASC (Behavioral Assessment System for Children), The California Verbal Learning Test, California Verbal Learning Test-C (children) and the Test of Memory and Learning.

4. The contractor shall evaluate patients at the central campus of the National Institutes of Health, (10 Center Drive, Bethesda, Maryland 20892). Appropriate office space and examining room space will be provided by HAMB.
5. The Contractor shall score and code the test results and shall enter data into each existing data base on the WYLBUR system or the ISPF (Interactive System Productivity) system of the Center for Information Technology, NIH, or a substitute system approved by the PO, within 30 days after completion of the evaluation. The original records must be maintained at their original place of administration and shall be appropriately filed within two working days. The contractor shall handle all individual reports, like any other medical document, in a manner that guarantees patients' confidentiality and in compliance with policies established by the NIH Clinical Center.
6. The Contractor shall provide administrative support for the research projects such as typing of reports and submissions for publications; patient scheduling for research projects; literature searches and collection of scientific papers; copying of scientific papers and test materials; maintaining and updating a computerized reference library (e.g. EndNote); indexing and filing of test material, patient files and scientific papers.
7. The Contractor shall utilize the existing databases, within the Branch, that consist of previously collected assessments on functions indicated in point 3, to facilitate investigations into neuropsychological functioning, longitudinal changes in neurocognitive function, and the effects of CNS disease, treatment, and HIV disease progression. The contractor shall provide evidence of research and development towards further sophistication in the evaluation of age appropriate neuropsychological functions. This further sophistication can be accomplished through new ways of using and analyzing standard assessment instruments, and through the development of novel experimental neurocognitive techniques. These approaches should be cost-effective, and the validity and reliability of the approaches should be investigated.
8. The Contractor shall provide neurobehavioral measures through appropriate assessments to investigate the pathogenesis of the encephalopathy, dementia, or neuropsychological abnormalities in these patients, as directed by the PO. This may include exploring relations between neurobehavioral measures and psychiatric, neurologic, developmental, biochemical, virologic, genetic, and physiologic variables. More sensitive neuroimaging studies shall be assessed and subsequently included in new and ongoing protocols.
9. The Contractor shall develop and evaluate psychologic and behavioral interventions for neurobehavioral conditions associated with HIV disease and its treatment in children and adults, as directed by the PO.
10. The Contractor shall investigate environmental factors that may underlie the pathogenesis of CNS disease, natural history, and response to treatment, as directed by the PO. Such factors may include family and peer relationships, school and academic achievement, and socioeconomic issues.
11. The Contractor shall present and co-author, in collaboration with the PO, other senior staff members of HAMB, and /or other CCR staff as appropriate, the results of these investigations at appropriate scientific meetings and in peer-reviewed scientific journals. The Contractor will keep the PO apprised of research and anticipated publications and presentations on an ongoing basis. All anticipated papers, abstracts, and other publications will go through the usual review procedures of HAMB and the CCR prior to submission. Because of the nature of the work done

in the contract, it is expected that except under unusual circumstances, publications will include one or more HAMB staff as co-authors.

12. The Contractor shall if requested assist in the integration of the neuropsychological findings from the HAMB, CCR, NCI into the protocols of national AIDS Clinical Trials Group and other national or international organizations, and where appropriate, collaborate with these groups.
13. Contractors must ensure that they comply with all applicable federal and state government regulations regarding control of infectious diseases in health care facilities, prior to the award of the contract. Contractors should consult the specific regulations for further details, exemptions, documentation, and record keeping requirements. (i.e., Health-General Article 19-307, Annotated Code of Maryland); OSHA Standards for Occupational Exposure to Bloodborne Pathogens). See Exhibit A - "Regulations Regarding Control of Infectious Diseases in Health Care Facilities".

[**EXHIBIT 1 – Regulations Regarding Control of Infectious Diseases in Health Care Facilities**](#), dated 10/28/03, 2 pages.

[**EXHIBIT 2 – Entry Form for Pediatric Neuropsychological Data**](#), dated 10/28/03, 15 pages.